

Claims

[c1] 1. A method of making a collection device for cells comprising of:

providing a tube having an open end and a closed end;

preloading compounds including:

an anticoagulant agent, and

a fixative agent into said tube, said fixative agent selected from the group consisting of: diazolidinyl urea,

imidazolidinyl urea, dimethoyl-5,5dimethylhydantoin,

dimethylol urea, 2-bromo-2-nitropropane-1,3-diol,

oxazolidines, sodium hydroxymethyl glycinate,

5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo

[3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7dioxabicyclo

[3.3.0]octane,

5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7dioxabi

cyclo [3.3.0]octane, quaternary adamantine and combinations thereof;

wherein said compounds are in a sufficient amount to

preserve said cells" original morphology and antigenic

sites without significant dilution of said cells, and

thereby allowing said cells to be directly analyzed by a

flow cytometer without further treatment;

inserting a closure into said open end of said tube; and

drawing a vacuum inside said tube to a predetermined level to form said collection device.

- [c2] 2. The method of Claim 1, wherein said anticoagulant agent is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin, heparin, citric acid, salts of citric acid, oxalic acid, salts of oxalic acid, and a combination thereof.
- [c3] 3. The method of Claim 1, wherein concentration of said fixative agent is less than about 1 g/ml.
- [c4] 4. The method of Claim 1, wherein concentration of said anticoagulant agent is less than about 0.3 g/ml.
- [c5] 5. The method of Claim 1, wherein said preloading step includes preloading a polyacrylic acid into said tube.
- [c6] 6. The method of Claim 1, wherein ratio of said compounds and a final composition comprising said cells and said compounds is less than about 2:100.
- [c7] 7. The method of Claim 1, wherein said cells are selected from the group consisting of epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.
- [c8] 8. The method of Claim 1, further comprising of steriliz-

ing said compounds before said compounds are preloaded into said tube.

[c9] 9. The method of Claim 1, further comprising of sterilizing at least all surface areas of said tube and said closure that can come into physical contact with said collected and preserved cells before said compounds are preloaded into said tube.

[c10] 10. The method of Claim 1, further comprising of providing at least one component selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis, a packaging means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

[c11] 11. The method of Claim 1, wherein said preloading step further comprises of freeze drying said compounds inside said tube.

[c12] 12. The method of Claim 1, further comprising of screening said collected and preserved cells using an instrument selected from the group consisting of: a flow cytometer, a hematology analyzer, H3 by Bayer Corpora-

tion, the Beckman Coulter STKS System, the Beckman Coulter Gen-S System, the Abbott Cell-Dyn 4000 Hematology System, Bayer ADVIA 120 System, the Sysmex XE2100 System, and other analyzers and a combination thereof.

[c13] 13. The method of Claim 1, further comprising of screening said collected and preserved cells for a purpose selected from the group consisting of: HIV, HPV, hepatitis, leukemia, cancer, and a combination thereof.

[c14] 14. A collection device for cells comprising of:
a collection container comprising of a tube having an open end and a closed end, a closure in said open end of said tube, a vacuum drawn to a predetermined level inside said container; and
compounds including an anticoagulant agent and a fixative agent selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethoylol-5,5dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7dioxabicyclo [3.3.0]octane, quaternary adamantane and combi-

nations thereof, inside said tube, wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells, and thereby allowing said cells to be directly analyzed by a flow cytometer without further treatment.

- [c15] 15. The device of Claim 14, wherein said anticoagulant agent is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin, heparin, citric acid, salts of citric acid, oxalic acid, salts of oxalic acid, and a combination thereof.
- [c16] 16. The device of Claim 14, wherein concentration of said fixative agent is less than about 1 g/ml.
- [c17] 17. The device of Claim 14, wherein concentration of said anticoagulant agent is less than about 0.3 g/ml.
- [c18] 18. The device of Claim 14, wherein compounds further includes a polyacrylic acid.
- [c19] 19. The device of Claim 14, wherein ratio of said compounds and a final composition comprising said cells and said compounds is less than about 2:100.
- [c20] 20. The device of Claim 14, wherein said cells are se-

lected from the group consisting of epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.

[c21] 21. The device of Claim 14, wherein said compounds are sterile.

[c22] 22. The device of Claim 14, wherein at least all surface areas of said tube and said closure that can come into physical contact with said cells are sterile.

[c23] 23. A kit comprising the device of Claim 14 and further comprising of at least one component selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis, a packaging means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

[c24] 24. The device of Claim 14 wherein compounds contained in said tube are freeze dried.

[c25] 25. The device of Claim 14 wherein said device is used along with an instrument selected from the group consisting of: a flow cytometer, a hematology analyzer, H3 by Bayer Corporation, the Beckman Coulter STKS System,

the Beckman Coulter Gen-S System, the Abbott Cell-Dyn 4000 Hematology System, Bayer ADVIA 120 System, the Sysmex XE2100 System, and a combination thereof to provide screening of said cells.

[c26] 26. The device of claim 14 wherein said device is used in screening said cells for a purpose selected from the group consisting of: HIV, HPV, hepatitis, leukemia, cancer, and a combination thereof.

[c27] 27. A method for transporting cells for analysis, said method comprising:
providing a collection container under vacuum; and containing compounds including an anticoagulant agent and a fixative agent selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethoyl-5,5dimethylhydantoin, dimethylol urea, 2-bromo-2-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7dioxabicyclo [3.3.0]octane, quaternary adamantane and combinations thereof inside said tube, wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilu-

tion of said cells,
collecting said cells in said collection container and;
transporting said cells for analysis.